

**Inamed Corporation
Modular Submission M010040
McGhan Silicone-Filled Breast Implants**

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**1990 MCGHAN MEDICAL CORPORATION
MAMMARY IMPLANT CLINICAL STUDY
RECONSTRUCTION COHORT**

FINAL REPORT

December 13, 2002

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Attachment 16

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MAMMARY IMPLANT CLINICAL STUDY
RECONSTRUCTION COHORT

TABLE OF CONTENTS

INTRODUCTION.....	3
METHODS.....	3
RESULTS.....	4
CONCLUSIONS.....	5
AR90 RECONSTRUCTION TABLES.....	6
AR90 RECONSTRUCTION APPENDICES.....	82
APPENDIX A.....	83
Investigational Sites by Principal Investigator, Facility, and Institutional Review Board	
APPENDIX B.....	94
Patient Enrollment by Implanting Site and Implanting Physician	
APPENDIX C.....	96
Distribution of Product Styles by Investigator	
APPENDIX D.....	99
Patient Discontinuation Forms	

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INTRODUCTION

The 1990 McGhan Medical Corporation Mammary Implant Clinical Study (AR90) is being submitted in order to provide safety and effectiveness data in support of this PMA for McGhan Silicone-Filled Breast Implants. AR90 is a five-year, prospective, multi-center clinical trial of saline-filled and silicone-filled breast implants for augmentation and reconstruction. The final report of 5-year results obtained for patients enrolled with McGhan Saline-Filled Breast Implants in this study was submitted to FDA on November 15, 1999 as part of the McGhan Medical PMA for saline-filled breast implants (PMA #P990074). This report presents the results of data obtained from reconstruction patients implanted with McGhan Silicone-Filled Breast Implants only.

METHODS

Thirty-four (34) reconstruction patients were enrolled (i.e., implanted) with silicone-filled breast implants by 13 investigators. This report presents data obtained from 29 patients; 5 patients are not included because they did not meet the eligibility criteria (these 5 patients had a previous breast implant procedure). These patients continued to be followed for safety events after implantation. Appendix A provides facility and IRB information for all study investigators for both the augmentation and reconstruction cohorts, including both implanting investigators and non-implanting investigators who later joined the study for the purpose of following patients who were originally enrolled by a different physician. Appendices B and C provide detailed patient/implant enrollment information for each implanting investigator for the reconstruction cohort. Appendix D provides copies of patient discontinuation forms. Discontinuation forms were not completed by sites for patients who were explanted of all primary study devices and replaced with other study devices; these patients continued to be followed for safety events after replacement.

Inamed is currently selling only 4 of the 11 device styles included in this study (Styles 40, 110, 120, and 153). The following devices were used in this study:

Silicone-Filled Devices

- Style 40 - round, smooth
- Style 80 - round, smooth
- Style 110 - round, textured
- Style 120 - round, textured
- Style 148 - round, textured
- Style 153 - shaped, textured
- Style 246 - round, smooth

Silicone/Saline-Filled Devices

- Style 46 - round, smooth
- Style 156 - round, textured
- Style 178 - round, textured
- Style 278 - round, smooth

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The procedures for data collection in this study were similar to those described in the Procedures for Data Collection section of the Adjunct Clinical Study Reports included in this PMA submission, except for the following:

- AR90 patient follow-up occurred annually through 5 years.
- AR90 includes a more in-depth effectiveness assessment (i.e., patient-completed Quality of Life questionnaire and bra size measurement). However, effectiveness analyses were not conducted for the reconstruction cohort because the number of patients was too small to allow any meaningful statistics. This is consistent with the presentation of the 5-year AR90 saline results in the McGhan Medical PMA for saline-filled breast implants (PMA #P990074, approved May 10, 2000).

The general approach for data analysis in this study is similar to the methods described in the General Analysis Approach section of the Adjunct Clinical Study Reports included in this PMA submission, except for the following:

- Data reported is for the complete cohort of patients through the final 5-year visit interval.
- The extract of the database housing the data used for this report was taken on October 19, 1999.

The specific data analysis methods used in this study are similar to those described in the Methods for Data Analysis section of the Adjunct Clinical Study Reports included in this PMA submission, except for the following:

- Adjusted patient compliance is calculated based only on primary study devices. When a patient undergoes removal of all primary study devices (with or without replacement), the patient appears in the "Cumulative Removal" category and is not considered in the denominator of the adjusted compliance calculation. This method for calculating adjusted compliance is identical to the method used to present the 5-year AR90 saline results in the McGhan Medical PMA for saline-filled breast implants (PMA #P990074, approved May 10, 2000).
- Bilaterally implanted patients were discontinued from the study if they had one of their implants removed and replaced with a non-McGhan device.

RESULTS

The results of this clinical study are provided in Tables 1 – 75. A breakdown of the specific results presented in these tables is as follows:

- Tables 1 – 4: Demographic Information
- Tables 5 - 16: Device Distribution
- Tables 17 – 23: Surgical Treatment Characteristics
- Table 24: Surgeon's Assessment of Initial Implant Surgery
- Tables 25 – 26: Follow-Up Compliance and Patient Discontinuation
- Tables 27 – 34: Secondary Procedures
- Tables 35 – 36: Capsular Contracture
- Table 37: Implant Rupture

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- Tables 38 – 43: Implant Replacement/Removal
- Tables 44 – 64: Other Medical Complications
- Tables 65 – 68: Reproduction and Lactation Problems
- Tables 69 – 70: Breast Disease and Connective Tissue/Autoimmune Disease
- Tables 71 – 72: Changes in Bra Size
- Tables 73 – 75: Satisfaction with Outcome

There were no Unanticipated Adverse Events (UAEs) associated with the silicone-filled breast implants for any of the reconstruction patients in this study. Four (4) UAE forms were completed by investigators for reconstruction patients. These forms were reviewed by the Medical Monitor who determined that the events reported (e.g., breast pain) did not meet the definition of a UAE.

There were no patient deaths reported in this study.

CONCLUSIONS

For the 29 reconstruction patients in this study who were followed for 5 years post-implant, the results revealed that McGhan Silicone-Filled Breast Implants are both safe and effective devices.

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AR90 RECONSTRUCTION TABLES

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Table 1: Patient Age

Age	Patients (N = 29)	
	n	%
18-19	0	0.0%
20-29	2	6.9%
30-39	7	24.1%
40-49	15	51.7%
50-59	3	10.3%
60-69	2	6.9%
	29	100.0%

Median = 43 years
Range = 28 to 65

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Table 2: Patient Race and Marital Status

Characteristic	Patients (N = 29)	
	n	%
Race		
Caucasian	27	93.1%
African-American	2	6.9%
Other	0	0.0%
	<hr/> 29	<hr/> 100.0%
Marital Status		
Single	5	17.2%
Married	20	69.0%
Widowed	0	0.0%
Separated	0	0.0%
Divorced	4	13.8%
Other	0	0.0%
	<hr/> 29	<hr/> 100.0%

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Table 3: Patient Occupation and Education

Characteristic	Patients (N = 29)	
	n	%
Occupation		
Clerical	7	24.1%
Professional	10	34.5%
Trade	1	3.4%
Manual Labor	1	3.4%
Student	0	0.0%
Housewife	5	17.2%
Other	5	17.2%
	<u>29</u>	<u>100.0%</u>
Education		
High School	0	0.0%
Some College	5	17.2%
College Graduate	10	34.5%
Post College	10	34.5%
Other	4	13.8%
	<u>29</u>	<u>100.0%</u>

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Table 4: Patient Pre-Implant Height and Weight

Characteristic	Patients (N = 29)	
	n	%
Height		
4'11" & under	2	6.9%
5'0" & 5'2"	1	3.4%
5'3" & 5'5"	12	41.4%
5'6" & 5'8"	13	44.8%
5'9" & 5'11"	1	3.4%
6'0" & over	0	0.0%
	29	100.0%
Median = 5'5"		
Range = 4'6" to 5'9"		
Weight		
99 lbs & under	0	0.0%
100-109	2	6.9%
110-119	5	17.2%
120-129	2	6.9%
130-139	9	31.0%
140-149	3	10.3%
150-159	2	6.9%
160 & over	6	20.7%
	29	100.0%
Median = 134 lbs		
Range = 107 to 280 lbs		

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Table 5: Product Styles

Product Styles	Implants (N = 43)	
	n	%
Style 40	0	0.0%
Style 46	2	4.7%
Style 80	0	0.0%
Style 110	3	7.0%
Style 120	2	4.7%
Style 148	0	0.0%
Style 153	27	62.8%
Style 156	2	4.7%
Style 178	6	14.0%
Style 246	1	2.3%
Style 278	0	0.0%

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Table 6: Product Style 40

Size	Implants (N = 0)	
	n	%
<hr/>		

There were no Style 40's enrolled in the reconstruction cohort

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Table 7: Product Style 46

Size	Implants (N = 2)	
	n	%
450	2	100.0%
	<u>2</u>	<u>100.0%</u>

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Table 8: Product Style 80

Size	Implants (N = 0)	
	n	%

There were no Style 80's enrolled in the reconstruction cohort

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Table 9: Product Style 110

Size	Implants (N = 3)	
	n	%
360	2	66.7%
480	1	33.3%
	3	100.0%

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Table 10: Product Style 120

Size	Implants (N = 2)	
	n	%
400	1	50.0%
500	1	50.0%
	2	100.0%

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Table 11: Product Style 148

Size	Implants (N = 0)	
	n	%

There were no Style 148's enrolled in the reconstruction cohort

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Table 12: Product Style 153

Size	Implants (N = 27)	
	n	%
360	4	14.8%
450	7	25.9%
540	8	29.6%
630	6	22.2%
720	2	7.4%
	<u>27</u>	<u>100.0%</u>

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Table 13: Product Style 156

Size	Implants (N = 2)	
	n	%
360	1	50.0%
525	1	50.0%
	2	100.0%

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Table 14: Product Style 178

Size	Implants (N = 6)	
	n	%
180	1	16.7%
260	1	16.7%
360	2	33.3%
380	2	33.3%
	6	100.0%

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Table 15: Product Style 246

Size	Implants (N = 1)	
	n	%
400	1	100.0%
	<u>1</u>	<u>100.0%</u>

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Table 16: Product Style 278

Size	Implants (N = 0)	
	n	%

There were no Style 278's enrolled in the reconstruction cohort

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Table 17: Indications for Procedure

Indication for Procedure	Patients (N = 29)	
	n	%
Mastectomy for Cancer	19	65.5%
Prophylactic Mastectomy	9	31.0%
Unilateral Augmentation to Treat Poland's Syndrome	1	3.4%
	29	100.0%

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Table 18: Procedure Performed

Procedure	Patients (N = 29)	
	n	%
Reconstruction Only	27	93.1%
Reconstruction with Contralateral Augmentation	2	6.9%
	29	100.0%

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Table 19: Type of Anesthesia and Surgical Facility

Characteristic	Patients (N = 29)	
	n	%
Anesthesia		
General	28	96.6%
Local	1	3.4%
	<u>29</u>	<u>100.0%</u>
Facility		
Doctor's Office	1	3.4%
Free Standing Surgi-Center	3	10.3%
Hospital Out-Patient	14	48.3%
Hospital In-Patient	11	37.9%
	<u>29</u>	<u>100.0%</u>

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Table 20: Surgical Characteristics

Characteristic	Implants (N = 43)	
	n	%
Incision Site		
Areolar	3	7.0%
Inframammary	6	14.0%
Axillary	0	0.0%
Mastectomy Scar	34	79.1%
	<hr/> 43	<hr/> 100.0%
Implant Placement		
Subglandular	1*	2.3%
Submuscular	42	97.7%
	<hr/> 43	<hr/> 100.0%

* Augmentation of contralateral breast

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Table 21: Concomitant Procedures

Procedure	Patients (N = 29)	
	n	%
No Concomitant Procedures	17	58.6%
Concomitant Procedures (Recon=12 Patients)*		
Breast Related (Implanted Side)		
Biopsy/Lump Removal	0	0.0%
Mastopexy	0	0.0%
Nipple-Related Procedures	6	20.7%
Capsule Treatment	3	10.3%
Reduction	1	3.4%
Removal of Skin Lesion	0	0.0%
Skin Flap	1	3.4%
Muscle Flap	1	3.4%
Other	1	3.4%
	13	44.8%
Breast Related (Non-Implanted Side)		
Biopsy/Lump Removal	0	0.0%
Mastopexy	0	0.0%
Nipple-Related Procedures	0	0.0%
Reduction	0	0.0%
	0	0.0%
Non-Breast Related		
Facial Plastic Surgery	0	0.0%
Bodily Plastic Surgery	0	0.0%
Other	0	0.0%
	0	0.0%

* The sum of patients with concomitant procedures is greater than the number of patients who had concomitant procedures because a patient may have had more than one concomitant procedure.

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Table 22: Intraoperative Medications by Route of Administration

Type of Medication	Patients (N = 29)	
	n	%
Pocket Irrigation		
Steroid	2	6.9%
Antibiotic	5	17.2%
Betadine	15	51.7%
Other Antiseptic	0	0.0%
None	8	27.6%
	<u>30</u>	<u>103.4%</u>
Within Implant		
Steroid	0	0.0%
Antibiotic	3	10.3%
Betadine	0	0.0%
None	26	89.7%
	<u>29</u>	<u>100.0%</u>
Other Routes of Administration		
Oral Antibiotic	0	0.0%
Parenteral Antibiotic	17	58.6%
Steroid	2	6.9%
None	12	41.4%
	<u>31</u>	<u>106.9%</u>

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Table 23: Operative Complications

Operative Complications	Patients (N = 29)	
	n	%
No Complications	29	100.0%
Complications	0	0.0%
	<u>29</u>	<u>100.0%</u>

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Table 24: Surgeon's Assessment of Initial Implant Surgery

Surgeon's Assessment	Implants (N = 43)	
	n	%
Definitely Satisfied	22	51.2%
Satisfied	21	48.8%
Somewhat Satisfied	0	0.0%
Somewhat Dissatisfied	0	0.0%
Definitely Dissatisfied	0	0.0%
	43	100.0%

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Table 25: Follow-Up Compliance

Study Interval	Patients Enrolled (N = 29)				
	Patients Seen	Unadjusted Compliance	Cumulative* Deaths	Cumulative* Removals	Adjusted** Compliance
	n	%	n	n	%
0-4 Weeks	29	100.0%	0	0	100.0%
6 Months	28	96.6%	0	0	96.6%
1 Year	27	93.1%	0	2	100.0%
2 Years	23	79.3%	0	4	92.0%
3 Years	21	72.4%	0	5	87.5%
4 Years	21	72.4%	0	5	87.5%
5 Years	18	62.1%	0	6	78.3%

* Cumulative deaths/removals refers to the total number of deaths/removals prior to the beginning of the study interval.

** Adjusted compliance excludes from the denominator of the calculation any patients who died or had all primary study implants removed prior to the beginning of the study interval.

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Table 26: Patient Discontinuation Through Five Years

Characteristic	Patients (N = 29)	
	n	%
Not Discontinued	22	75.9%
Discontinued		
Death	0	0.0%
Removal of Primary Implants	6	20.7%
Chose to Discontinue	1	3.4%
	29	100.0%

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Table 27: Number of Secondary Treatment Visits Through Five Years

Secondary Treatment Visits	Patients (N = 29)		Implants (N = 43)	
	n	%	n	%
No Secondary Treatment Visits	12	41.4%	20	46.5%
At Least One Secondary Treatment Visit	17	58.6%	23	53.5%
	29	100.0%	43	100.0%
Secondary Treatment Visit Breakdown				
1 Visit	11	64.7%	17	73.9%
2 Visits	5	29.4%	5	21.7%
3 or More Visits	1	5.9%	1	4.3%
	17	100.0%	23	100.0%
Total Secondary Treatment Visits	24 patient visits*		30 implant visits**	

* Total number of secondary patient treatment visits is calculated as:
 (11 x 1 visit) + (5 x 2 visits) + (1 x 3 visits) = 24 patient visits

** Total number of secondary implant treatment visits is calculated as:
 (17 x 1 visit) + (5 x 2 visits) + (1 x 3 visits) = 30 implant visits

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Table 28: Number of Procedures Per Secondary Treatment Visit
 Through Five Years

Number of Treatments	Patient Treatment Visits (N = 24)		Implant Treatment Visits (N = 30)	
	n	%	n	%
Procedure Performed Breakdown				
1 Procedure	17	70.8%	29	96.7%
2 Procedures	7	29.2%	1	3.3%
3 or More Procedures	0	0.0%	0	0.0%
	<u>24</u>	<u>100.0%</u>	<u>30</u>	<u>100.0%</u>
Total Secondary Procedures Performed	31 procedures by patient*		31 procedures by implant**	

* Total number of secondary procedures performed by patient is calculated as: (1 procedure x 17) + (2 procedures x 7) = 31 procedures

** Total number of secondary procedures performed by implant is calculated as: (1 procedure x 29) + (2 procedures x 1) = 31 procedures

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Table 29: Operative Complications for Each Secondary Patient
Treatment Visit Through Five Years

Operative Complications	Patient Treatment Visits (N = 24)	
	n	%
No Operative Complications	24	100.0%
Operative Complications	0	0.0%
	<hr/> 24	<hr/> 100.0%

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Table 30: Surgeon's Assessment of Each Secondary Implant Treatment Visit Through Five Years

Surgeon's Assessment	Implant Treatment Visits (N = 30)	
	n	%
Definitely Satisfied	13	43.3%
Satisfied	12	40.0%
Somewhat Satisfied	2	6.7%
Somewhat Dissatisfied	0	0.0%
Definitely Dissatisfied	0	0.0%
Missing	3	10.0%
	<hr/> 30	<hr/> 100.0%

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Table 31: Risk of First Occurrence of Any Secondary Procedure

Time	By Patient				By Implant			
	Number		n	Cumulative Risk % (95% CI)	Number		n	Cumulative Risk % (95% CI)
	Affected	Remaining			Affected	Remaining		
4 Weeks	0	29	0.0%	0	49	0.0%	--	
6 Months	7	22	24.1% (8.6%, 39.7%)	10	33	23.3% (10.6%, 35.9%)	--	
1 Year	11	18	37.9% (20.3%, 55.6%)	15	28	34.9% (20.6%, 49.1%)	--	
2 Years	15	13	51.7% (33.5%, 69.9%)	21	20	48.8% (33.9%, 63.8%)	--	
3 Years	15	13	51.7% (33.5%, 69.9%)	21	20	48.8% (33.9%, 63.8%)	--	
4 Years	16	12	55.4% (37.3%, 73.6%)	22	19	51.4% (36.4%, 66.4%)	--	
5 Years	17	8	59.9% (41.5%, 78.2%)	23	12	54.6% (39.3%, 69.9%)	--	

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Table 32: Risk of First Occurrence of Implant Related Secondary Procedure.

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk		
	n	n	% (95% CI)	n	n	% (95% CI)		
4 Weeks	0	29	0.0%	0	43	0.0%	--	
6 Months	1	28	3.4% (0.0%, 10.1%)	1	42	2.3% (0.0%, 6.8%)	--	
1 Year	5	24	17.2% (3.5%, 31.0%)	5	37	11.9% (2.1%, 21.6%)	--	
2 Years	9	19	31.0% (14.2%, 47.9%)	11	29	26.1% (12.9%, 39.4%)	--	
3 Years	9	19	31.0% (14.2%, 47.9%)	11	29	26.1% (12.9%, 39.4%)	--	
4 Years	11	17	38.3% (20.5%, 56.1%)	13	27	31.2% (17.1%, 45.4%)	--	
5 Years	11	11	38.3% (20.5%, 56.1%)	13	18	31.2% (17.1%, 45.4%)	--	

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Table 33: Risk of First Occurrence of Non-Implant Related Secondary Procedure

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	29	0.0%	--	0	43	0.0%	--
6 Months	6	22	21.3%	(6.2%, 36.5%)	9	33	21.3%	(9.0%, 33.7%)
1 Year	9	18	32.1%	(14.8%, 49.3%)	13	28	30.9%	(16.9%, 44.8%)
2 Years	9	13	32.1%	(14.8%, 49.3%)	13	20	30.9%	(16.9%, 44.8%)
3 Years	9	13	32.1%	(14.8%, 49.3%)	13	20	30.9%	(16.9%, 44.8%)
4 Years	9	12	32.1%	(14.8%, 49.3%)	13	19	30.9%	(16.9%, 44.8%)
5 Years	10	8	38.9%	(18.8%, 58.9%)	14	12	35.5%	(19.8%, 51.2%)

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Table 34: Types of Secondary Procedures Performed Through Five Years

Types of Secondary Procedures	n	% (N = 31)
Implant Related Procedures		
Aspiration	0	0.0%
Capsule Procedure		
Capsulectomy	1	3.2%
Capsulorrhaphy	0	0.0%
Capsulotomy	0	0.0%
Other Capsule Procedure	0	0.0%
Change Saline Fill		
Add Saline	0	0.0%
Remove Saline	0	0.0%
Implant Removal		
With Replacement	9	29.0%
Without Replacement	3	9.7%
Mastopexy	0	0.0%
Reposition Implant	0	0.0%
Scar Revision	1	3.2%
Wound Repair	0	0.0%
Other	1	3.2%
	<hr/> 15	<hr/> 48.4%
Non-Implant Related Procedures		
Biopsy/Lump Removal	1	3.2%
Mastectomy	0	0.0%
Nipple-Related Procedure	14	45.2%
Removal of Skin Lesion/Cyst	1	3.2%
Skin Adjustment	0	0.0%
Muscle Flap	0	0.0%
Bodily Plastic Surgery	0	0.0%
	<hr/> 16	<hr/> 51.6%

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Table 35: Risk of First Occurrence of Capsular Contracture*

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0%	29	0.0%	0	0.0%	43	0.0%
6 Months	0	0.0%	28	0.0%	0	0.0%	42	0.0%
1 Year	0	0.0%	26	0.0%	0	0.0%	39	0.0%
2 Years	1	4.5% (0.0%, 13.2%)	20	4.5% (0.0%, 13.2%)	1	3.0% (0.0%, 8.9%)	30	3.0% (0.0%, 8.9%)
3 Years	1	4.5% (0.0%, 13.2%)	20	4.5% (0.0%, 13.2%)	1	3.0% (0.0%, 8.9%)	30	3.0% (0.0%, 8.9%)
4 Years	1	4.5% (0.0%, 13.2%)	19	4.5% (0.0%, 13.2%)	1	3.0% (0.0%, 8.9%)	29	3.0% (0.0%, 8.9%)
5 Years	1	4.5% (0.0%, 13.2%)	13	4.5% (0.0%, 13.2%)	1	3.0% (0.0%, 8.9%)	20	3.0% (0.0%, 8.9%)

* Capsular Contracture is defined as a physician evaluation of a capsule as a III or IV on the Baker Grade Classification scale. If a Baker Grade was not given but 1) capsular contracture was reported specifically, or 2) a capsule treatment was performed and firmness was reported, Baker Grade was assumed to be Grade IV.

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Table 36: Worst Case Baker Grade Observed During Each Study Interval
 (by Patient)

Study Interval	Baker Classification Score				
	Baker Patients	Baker I	Baker II	Baker III	Baker IV
	n	%	%	%	%
0-4 Weeks	29	58.6%	41.4%	0.0%	0.0%
6 Months	28	64.3%	35.7%	0.0%	0.0%
1 Year	26	61.5%	38.5%	0.0%	0.0%
2 Years	23	65.2%	30.4%	4.3%	0.0%
3 Years	21	76.2%	19.0%	4.8%	0.0%
4 Years	20	60.0%	35.0%	0.0%	5.0%
5 Years	18	72.2%	16.7%	0.0%	11.1%

* If no Baker Grade was given for a visit but capsular contracture was indicated specifically, or if a capsule treatment was performed to correct firmness and no Baker Grade was given, Baker Grade was assumed to be Grade IV.

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Table 37: Risk of First Occurrence of Implant Rupture

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk
4 Weeks	0	29	0.0% ..	0	43	0.0% ..
6 Months	0	28	0.0% ..	0	42	0.0% ..
1 Year	0	26	0.0% ..	0	39	0.0% ..
2 Years	0	21	0.0% ..	0	31	0.0% ..
3 Years	1	20	4.8% (0.0%, 13.9%)	1	30	3.2% (0.0%, 9.4%)
4 Years	1	19	4.8% (0.0%, 13.9%)	1	29	3.2% (0.0%, 9.4%)
5 Years	2	13	10.7% (0.0%, 24.9%)	2	20	7.3% (0.0%, 17.0%)

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Table 38: Risk of First Occurrence of Implant Replacement/Removal

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0%	29	0.0%	0	0.0%	43	0.0%
6 Months	1	3.4% (0.0%, 10.1%)	28	3.4% (0.0%, 10.1%)	1	2.3% (0.0%, 6.8%)	42	2.3% (0.0%, 6.8%)
1 Year	3	10.3% (0.0%, 21.4%)	26	10.3% (0.0%, 21.4%)	3	7.1% (0.0%, 14.8%)	39	7.1% (0.0%, 14.8%)
2 Years	7	24.1% (8.6%, 39.7%)	21	24.1% (8.6%, 39.7%)	9	21.4% (9.0%, 33.8%)	31	21.4% (9.0%, 33.8%)
3 Years	7	24.1% (8.6%, 39.7%)	21	24.1% (8.6%, 39.7%)	9	21.4% (9.0%, 33.8%)	31	21.4% (9.0%, 33.8%)
4 Years	10	35.0% (17.5%, 52.5%)	18	35.0% (17.5%, 52.5%)	12	29.0% (15.1%, 42.9%)	28	29.0% (15.1%, 42.9%)
5 Years	10	35.0% (17.5%, 52.5%)	12	35.0% (17.5%, 52.5%)	12	29.0% (15.1%, 42.9%)	19	29.0% (15.1%, 42.9%)

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Table 39: Risk of First Occurrence of Implant Replacement/Removal to Treat a Complication

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	29	0.0%	--	0	43	0.0%	--
6 Months	0	28	0.0%	--	0	42	0.0%	--
1 Year	1	26	3.6%	(0.0%, 10.4%)	1	39	2.4%	(0.0%, 7.2%)
2 Years	2	21	7.6%	(0.0%, 17.7%)	3	31	7.9%	(0.0%, 16.4%)
3 Years	2	21	7.6%	(0.0%, 17.7%)	3	31	7.9%	(0.0%, 16.4%)
4 Years	3	19	12.0%	(0.0%, 24.8%)	4	29	10.8%	(0.8%, 20.9%)
5 Years	3	13	12.0%	(0.0%, 24.8%)	4	20	10.8%	(0.8%, 20.9%)

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Table 40: Risk of First Occurrence of Implant Replacement/Removal Due to Patient Choice

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	29	0.0%	--	0	43	0.0%	--
6 Months	1	28	3.4%	(0.0%, 10.1%)	1	42	2.3%	(0.0%, 6.8%)
1 Year	2	26	7.0%	(0.0%, 16.4%)	2	39	4.8%	(0.0%, 11.2%)
2 Years	5	21	18.2%	(3.7%, 32.6%)	6	31	15.1%	(3.9%, 26.2%)
3 Years	5	21	18.2%	(3.7%, 32.6%)	6	31	15.1%	(3.9%, 26.2%)
4 Years	7	19	26.0%	(9.4%, 42.6%)	8	29	20.5%	(7.8%, 33.3%)
5 Years	7	13	26.0%	(9.4%, 42.6%)	8	20	20.5%	(7.8%, 33.3%)

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Table 41: Primary Reason* for Implant Replacement/Removal Through Five Years

Primary Reason* for Implant Removal	Implant Removals (N = 12)	
	n	%
Removal To Treat a Complication		
Rupture/Deflation/Leakage	1	8.3%
Infection	1	8.3%
Capsular Contracture	0	0.0%
Wrinkling	0	0.0%
Breast Pain	2	16.7%
Unknown	0	0.0%
	<hr/> 4	<hr/> 33.3%
Removal Due to Patient Choice		
Change Size/Style	7	58.3%
Media-Related Anxiety	1	8.3%
	<hr/> 8	<hr/> 66.7%

* In the case where multiple reasons are given for implant removal, the primary reason is determined by classifying the response into a single category based on the hierarchy defined by the above ordering of complications and patient choice reasons. A complication takes precedence over patient choice as reason for implant removal.

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Table 42: Types of Replacement Implants Through Five Years

Type of Device	Implants Replaced (N = 9)	
	n	%
McGhan Study Device	0	0.0%
McGhan Non-Study Device	4	44.4%
Non-McGhan Device	5	55.6%
	<u>9</u>	<u>100.0%</u>

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Table 43: Replacement Implant Sizes Through Five Years

Replacement Implant Size	Implants Replaced With McGhan Study Devices (N = 0)	
	n	%
There were no devices replaced with McGhan Study Devices		

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Table 44: Risk of First Occurrence of Asymmetry

Time	By Patient		
	Number Affected	Number Remaining	Cumulative Risk
	n	n	% (95% CI)
4 Weeks	0	29	0.0% --
6 Months	2	27	6.9% (0.0%, 16.1%)
1 Year	3	24	10.3% (0.0%, 21.4%)
2 Years	3	19	10.3% (0.0%, 21.4%)
3 Years	3	19	10.3% (0.0%, 21.4%)
4 Years	3	18	10.3% (0.0%, 21.4%)
5 Years	3	12	10.3% (0.0%, 21.4%)

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Table 45: Risk of First Occurrence of Breast Pain

Time	By Patient				By Implant			
	Number Affected	Number Remaining	n	% (95% CI)	Number Affected	Number Remaining	n	% (95% CI)
4 Weeks	2	27	27	6.9% (0.0%, 16.1%)	3	40	40	7.0% (0.0%, 14.6%)
6 Months	2	26	26	6.9% (0.0%, 16.1%)	3	39	39	7.0% (0.0%, 14.6%)
1 Year	3	23	23	10.6% (0.0%, 22.0%)	5	34	34	12.1% (2.1%, 22.0%)
2 Years	4	19	19	14.5% (1.3%, 27.7%)	6	28	28	14.7% (3.8%, 25.5%)
3 Years	4	19	19	14.5% (1.3%, 27.7%)	6	28	28	14.7% (3.8%, 25.5%)
4 Years	4	18	18	14.5% (1.3%, 27.7%)	6	27	27	14.7% (3.8%, 25.5%)
5 Years	4	12	12	14.5% (1.3%, 27.7%)	6	18	18	14.7% (3.8%, 25.5%)

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Table 46: Risk of First Occurrence of Capsule Calcification

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	29	0.0%	0.0%	0	43	0.0%	--
6 Months	1	27	3.4%	(0.0%, 10.1%)	1	41	2.3%	(0.0%, 6.8%)
1 Year	1	25	3.4%	(0.0%, 10.1%)	1	38	2.3%	(0.0%, 6.8%)
2 Years	1	20	3.4%	(0.0%, 10.1%)	1	30	2.3%	(0.0%, 6.8%)
3 Years	1	20	3.4%	(0.0%, 10.1%)	1	30	2.3%	(0.0%, 6.8%)
4 Years	1	19	3.4%	(0.0%, 10.1%)	1	29	2.3%	(0.0%, 6.8%)
5 Years	1	13	3.4%	(0.0%, 10.1%)	1	20	2.3%	(0.0%, 6.8%)

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Table 47: Risk of First Occurrence of Delayed Wound Healing

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	29	0.0%	--	0	43	0.0%	--
6 Months	0	28	0.0%	--	0	42	0.0%	--
1 Year	0	26	0.0%	--	0	39	0.0%	--
2 Years	0	21	0.0%	--	0	31	0.0%	--
3 Years	0	21	0.0%	--	0	31	0.0%	--
4 Years	0	20	0.0%	--	0	30	0.0%	--
5 Years	0	14	0.0%	--	0	21	0.0%	--

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Table 48: Risk of First Occurrence of Hematoma

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	1	28	3.4%	(0.0%, 10.1%)	1	42	2.3%	(0.0%, 6.8%)
6 Months	1	27	3.4%	(0.0%, 10.1%)	1	41	2.3%	(0.0%, 6.8%)
1 Year	1	25	3.4%	(0.0%, 10.1%)	1	38	2.3%	(0.0%, 6.8%)
2 Years	1	20	3.4%	(0.0%, 10.1%)	1	30	2.3%	(0.0%, 6.8%)
3 Years	1	20	3.4%	(0.0%, 10.1%)	1	30	2.3%	(0.0%, 6.8%)
4 Years	1	19	3.4%	(0.0%, 10.1%)	1	29	2.3%	(0.0%, 6.8%)
5 Years	1	13	3.4%	(0.0%, 10.1%)	1	20	2.3%	(0.0%, 6.8%)

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Table 49: Risk of First Occurrence of Implant Extrusion

Time	By Patient				By Implant			
	Number		Cumulative Risk		Number		Cumulative Risk	
	Number Affected	Number Remaining	n	% (95% CI)	Number Affected	Number Remaining	n	% (95% CI)
4 Weeks	0	29	0	0.0%	0	43	0	0.0%
6 Months	0	28	0	0.0%	0	42	0	0.0%
1 Year	0	26	0	0.0%	0	39	0	0.0%
2 Years	0	21	0	0.0%	0	31	0	0.0%
3 Years	0	21	0	0.0%	0	31	0	0.0%
4 Years	0	20	0	0.0%	0	30	0	0.0%
5 Years	0	14	0	0.0%	0	21	0	0.0%

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Table 50: Risk of First Occurrence of Implant Malposition

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk
4 Weeks	0	29	0.0% --	0	43	0.0% --
6 Months	3	26	10.3% (0.0%, 21.4%)	3	40	7.0% (0.0%, 14.6%)
1 Year	3	24	10.3% (0.0%, 21.4%)	3	37	7.0% (0.0%, 14.6%)
2 Years	3	20	10.3% (0.0%, 21.4%)	3	30	7.0% (0.0%, 14.6%)
3 Years	3	20	10.3% (0.0%, 21.4%)	3	30	7.0% (0.0%, 14.6%)
4 Years	4	18	15.1% (1.2%, 28.9%)	4	28	10.2% (0.6%, 19.8%)
5 Years	5	11	19.8% (3.9%, 35.6%)	5	18	13.4% (2.3%, 24.5%)

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Table 51: Risk of First Occurrence of Implant Palpability/Visibility

Time	By Patient				By Implant			
	n	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	n	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	0	0	29	0.0% --	0	0	43	0.0% --
6 Months	0	0	28	0.0% --	0	0	42	0.0% --
1 Year	0	0	26	0.0% --	0	0	39	0.0% --
2 Years	0	0	21	0.0% --	0	0	31	0.0% --
3 Years	0	0	21	0.0% --	0	0	31	0.0% --
4 Years	0	0	20	0.0% --	0	0	30	0.0% --
5 Years	1	1	13	5.9% (0.0%, 17.1%)	1	1	20	4.0% (0.0%, 11.7%)

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Table 52: Risk of First Occurrence of Infection

Time	By Patient			By Implant		
	Number Affected	Number Remaining	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk
4 Weeks	0	29	0.0%	0	43	0.0%
6 Months	0	28	0.0%	0	42	0.0%
1 Year	0	26	0.0%	0	39	0.0%
2 Years	0	21	0.0%	0	31	0.0%
3 Years	0	21	0.0%	0	31	0.0%
4 Years	0	20	0.0%	0	30	0.0%
5 Years	0	14	0.0%	0	21	0.0%

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Table 53: Risk of First Occurrence of Irritation/Inflammation

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	29	0.0%	--	0	43	0.0%	--
6 Months	0	28	0.0%	--	0	42	0.0%	--
1 Year	0	26	0.0%	--	0	39	0.0%	--
2 Years	1	21	4.3%	(0.0%, 12.7%)	1	31	2.9%	(0.0%, 8.6%)
3 Years	2	20	8.9%	(0.0%, 20.7%)	2	30	6.1%	(0.0%, 14.2%)
4 Years	2	19	8.9%	(0.0%, 20.7%)	2	29	6.1%	(0.0%, 14.2%)
5 Years	2	14	8.9%	(0.0%, 20.7%)	2	21	6.1%	(0.0%, 14.2%)

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Table 54: Risk of First Occurrence of Loss of Nipple Sensation

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0%	29	0.0%	0	0.0%	43	0.0%
6 Months	1	3.4% (0.0%, 10.1%)	27	3.4% (0.0%, 10.1%)	1	2.3% (0.0%, 6.8%)	41	2.3% (0.0%, 6.8%)
1 Year	1	3.4% (0.0%, 10.1%)	25	3.4% (0.0%, 10.1%)	1	2.3% (0.0%, 6.8%)	38	2.3% (0.0%, 6.8%)
2 Years	1	3.4% (0.0%, 10.1%)	21	3.4% (0.0%, 10.1%)	1	2.3% (0.0%, 6.8%)	31	2.3% (0.0%, 6.8%)
3 Years	1	3.4% (0.0%, 10.1%)	21	3.4% (0.0%, 10.1%)	1	2.3% (0.0%, 6.8%)	31	2.3% (0.0%, 6.8%)
4 Years	1	3.4% (0.0%, 10.1%)	20	3.4% (0.0%, 10.1%)	1	2.3% (0.0%, 6.8%)	30	2.3% (0.0%, 6.8%)
5 Years	1	3.4% (0.0%, 10.1%)	14	3.4% (0.0%, 10.1%)	1	2.3% (0.0%, 6.8%)	21	2.3% (0.0%, 6.8%)

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Table 55: Risk of First Occurrence of Lymphadenopathy

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0%	29	0.0%	0	0.0%	43	0.0%
6 Months	0	0.0%	28	0.0%	0	0.0%	42	0.0%
1 Year	0	0.0%	26	0.0%	0	0.0%	39	0.0%
2 Years	0	0.0%	21	0.0%	0	0.0%	31	0.0%
3 Years	0	0.0%	21	0.0%	0	0.0%	31	0.0%
4 Years	0	0.0%	20	0.0%	0	0.0%	30	0.0%
5 Years	0	0.0%	14	0.0%	0	0.0%	21	0.0%

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Table 56: Risk of First Occurrence of Nipple Paresthesia

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	1	28	3.4%	(0.0%, 10.1%)	2	41	4.7%	(0.0%, 10.9%)
6 Months	1	27	3.4%	(0.0%, 10.1%)	2	40	4.7%	(0.0%, 10.9%)
1 Year	1	25	3.4%	(0.0%, 10.1%)	2	37	4.7%	(0.0%, 10.9%)
2 Years	1	21	3.4%	(0.0%, 10.1%)	2	31	4.7%	(0.0%, 10.9%)
3 Years	1	21	3.4%	(0.0%, 10.1%)	2	31	4.7%	(0.0%, 10.9%)
4 Years	1	20	3.4%	(0.0%, 10.1%)	2	30	4.7%	(0.0%, 10.9%)
5 Years	1	14	3.4%	(0.0%, 10.1%)	2	21	4.7%	(0.0%, 10.9%)

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Table 57: Risk of First Occurrence of Pneumothorax

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	29	0.0%	--	0	43	0.0%	--
6 Months	0	28	0.0%	--	0	42	0.0%	--
1 Year	0	26	0.0%	--	0	39	0.0%	--
2 Years	0	21	0.0%	--	0	31	0.0%	--
3 Years	0	21	0.0%	--	0	31	0.0%	--
4 Years	0	20	0.0%	--	0	30	0.0%	--
5 Years	0	14	0.0%	--	0	21	0.0%	--

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Table 58: Risk of First Occurrence of Scarring Complications

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0%	29	0.0%	0	0.0%	43	0.0%
6 Months	1	3.6% (0.0%, 10.4%)	27	3.6% (0.0%, 10.4%)	2	4.8% (0.0%, 11.2%)	40	4.8% (0.0%, 11.2%)
1 Year	2	7.3% (0.0%, 17.0%)	24	7.3% (0.0%, 17.0%)	3	7.3% (0.0%, 15.2%)	36	7.3% (0.0%, 15.2%)
2 Years	2	7.3% (0.0%, 17.0%)	19	7.3% (0.0%, 17.0%)	3	7.3% (0.0%, 15.2%)	28	7.3% (0.0%, 15.2%)
3 Years	2	7.3% (0.0%, 17.0%)	19	7.3% (0.0%, 17.0%)	3	7.3% (0.0%, 15.2%)	28	7.3% (0.0%, 15.2%)
4 Years	2	7.3% (0.0%, 17.0%)	18	7.3% (0.0%, 17.0%)	3	7.3% (0.0%, 15.2%)	27	7.3% (0.0%, 15.2%)
5 Years	2	7.3% (0.0%, 17.0%)	13	7.3% (0.0%, 17.0%)	3	7.3% (0.0%, 15.2%)	19	7.3% (0.0%, 15.2%)

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Table 59: Risk of First Occurrence of Seroma

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0%	29	0.0%	0	0.0%	43	0.0%
6 Months	0	0.0%	28	0.0%	0	0.0%	42	0.0%
1 Year	0	0.0%	26	0.0%	0	0.0%	39	0.0%
2 Years	0	0.0%	21	0.0%	0	0.0%	31	0.0%
3 Years	0	0.0%	21	0.0%	0	0.0%	31	0.0%
4 Years	0	0.0%	20	0.0%	0	0.0%	30	0.0%
5 Years	0	0.0%	14	0.0%	0	0.0%	21	0.0%

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Table 60: Risk of First Occurrence of Skin Paresthesia

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	1	3.4% (0.0%, 10.1%)	28	3.4% (0.0%, 10.1%)	2	4.7% (0.0%, 10.9%)	41	4.7% (0.0%, 10.9%)
6 Months	1	3.4% (0.0%, 10.1%)	27	3.4% (0.0%, 10.1%)	2	4.7% (0.0%, 10.9%)	40	4.7% (0.0%, 10.9%)
1 Year	2	7.3% (0.0%, 17.1%)	24	7.3% (0.0%, 17.1%)	3	7.2% (0.0%, 15.1%)	36	7.2% (0.0%, 15.1%)
2 Years	2	7.3% (0.0%, 17.1%)	20	7.3% (0.0%, 17.1%)	3	7.2% (0.0%, 15.1%)	29	7.2% (0.0%, 15.1%)
3 Years	2	7.3% (0.0%, 17.1%)	20	7.3% (0.0%, 17.1%)	3	7.2% (0.0%, 15.1%)	29	7.2% (0.0%, 15.1%)
4 Years	2	7.3% (0.0%, 17.1%)	19	7.3% (0.0%, 17.1%)	3	7.2% (0.0%, 15.1%)	28	7.2% (0.0%, 15.1%)
5 Years	2	7.3% (0.0%, 17.1%)	13	7.3% (0.0%, 17.1%)	3	7.2% (0.0%, 15.1%)	19	7.2% (0.0%, 15.1%)

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Table 61: Risk of First Occurrence of Skin Rash

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	1	28	3.4% (0.0%, 10.1%)	1	42	2.3% (0.0%, 6.8%)
6 Months	1	28	3.4% (0.0%, 10.1%)	1	42	2.3% (0.0%, 6.8%)
1 Year	1	26	3.4% (0.0%, 10.1%)	1	39	2.3% (0.0%, 6.8%)
2 Years	1	21	3.4% (0.0%, 10.1%)	1	31	2.3% (0.0%, 6.8%)
3 Years	2	20	8.0% (0.0%, 18.9%)	2	30	5.5% (0.0%, 13.0%)
4 Years	2	19	8.0% (0.0%, 18.9%)	3	28	8.6% (0.0%, 18.1%)
5 Years	2	14	8.0% (0.0%, 18.9%)	3	21	8.6% (0.0%, 18.1%)

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Table 62: Risk of First Occurrence of Tissue or Skin Necrosis

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	0	29	0.0%	0	43	0.0%
6 Months	1	27	3.6% (0.0%, 10.4%)	1	41	2.4% (0.0%, 7.0%)
1 Year	1	25	3.6% (0.0%, 10.4%)	1	38	2.4% (0.0%, 7.0%)
2 Years	1	20	3.6% (0.0%, 10.4%)	1	30	2.4% (0.0%, 7.0%)
3 Years	1	20	3.6% (0.0%, 10.4%)	1	30	2.4% (0.0%, 7.0%)
4 Years	1	19	3.6% (0.0%, 10.4%)	1	29	2.4% (0.0%, 7.0%)
5 Years	1	13	3.6% (0.0%, 10.4%)	1	20	2.4% (0.0%, 7.0%)

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Table 63: Risk of First Occurrence of Wrinkling

Time	By Patient				By Implant			
	Number		Cumulative Risk		Number		Cumulative Risk	
	Affected	Remaining	% (95% CI)		Affected	Remaining	% (95% CI)	
4 Weeks	0	29	0.0%	0.0%	0	43	0.0%	0.0%
6 Months	1	27	3.6% (0.0%, 10.4%)	3.6% (0.0%, 10.4%)	1	41	2.4% (0.0%, 7.0%)	2.4% (0.0%, 7.0%)
1 Year	3	23	11.0% (0.0%, 22.7%)	11.0% (0.0%, 22.7%)	3	36	7.4% (0.0%, 15.4%)	7.4% (0.0%, 15.4%)
2 Years	5	16	19.9% (4.1%, 35.7%)	19.9% (4.1%, 35.7%)	5	26	13.4% (2.4%, 24.4%)	13.4% (2.4%, 24.4%)
3 Years	5	16	19.9% (4.1%, 35.7%)	19.9% (4.1%, 35.7%)	5	26	13.4% (2.4%, 24.4%)	13.4% (2.4%, 24.4%)
4 Years	6	14	25.2% (7.4%, 43.1%)	25.2% (7.4%, 43.1%)	7	23	20.3% (6.6%, 34.0%)	20.3% (6.6%, 34.0%)
5 Years	7	8	32.0% (11.4%, 52.6%)	32.0% (11.4%, 52.6%)	8	15	24.7% (9.3%, 40.2%)	24.7% (9.3%, 40.2%)

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Table 64: Risk of First Occurrence of Other Complications

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk
4 Weeks	0	29	0.0% --	0	43	0.0% --
6 Months	0	28	0.0% --	0	42	0.0% --
1 Year	0	26	0.0% --	0	39	0.0% --
2 Years	1	20	4.3% (0.0%, 12.7%)	1	30	2.9% (0.0%, 8.6%)
3 Years	1	20	4.3% (0.0%, 12.7%)	1	30	2.9% (0.0%, 8.6%)
4 Years	1	19	4.3% (0.0%, 12.7%)	1	29	2.9% (0.0%, 8.6%)
5 Years	1	13	4.3% (0.0%, 12.7%)	1	20	2.9% (0.0%, 8.6%)

* The other complication as reported by the physician (by implant) was POSSIBLE FUNGUS.

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Table 65: Pre-Implant Reproduction Problems

Reproduction Problems	Patients (N = 29)	
	n	%
No Problems	20	69.0%
Problems	9	31.0%
	29	100.0%

Pt Seq#	Reproduction Problem
1	1 Spontaneous Abortion
2	1 Spontaneous Abortion
3	1 Spontaneous Abortion
4	3 Spontaneous Abortions
5	3 Spontaneous Abortions
6	3 Spontaneous Abortions
7	1 Spontaneous Abortion
8	1 Spontaneous Abortion
9	1 Spontaneous Abortion

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Table 66: Post-Implant Reproduction Problems Through Five Years

Reproduction Problems	Patients (N = 29)	
	n	%
No Problems	29	100.0%
Problems	0	0.0%
	29	100.0%

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Table 67: Pre-Implant Lactation Problems

Lactation Problems	Patients (N = 29)	
	n	%
No Problems	29	100.0%
Problems	0	0.0%
	29	100.0%

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Table 68: Post-Implant Lactation Problems Through Five Years

Lactation Problems	Patients (N = 29)	
	n	%
No Problems	29	100.0%
Problems	0	0.0%
	29	100.0%

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Table 69: Pre-Implant Breast Disease
& Connective Tissue/Autoimmune Disease

Breast Disease:

All patients underwent breast reconstruction following mastectomy due to breast cancer, prophylactic mastectomy, or to treat Poland's syndrome (see Table 17)

Connective Tissue/Autoimmune Disease:

No patients reported a pre-implant onset of connective tissue/ autoimmune disease

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Table 70: Post-Implant Breast Disease
 & Connective Tissue/Autoimmune Disease

Breast Disease	Patients (N = 29)	
	n	%
No Breast Disease	24	82.8%
Breast Disease		
Benign	3	10.3%
Malignant	2	6.9%
	29	100.0%

CTD	Patients (N = 29)	
	n	%
No CTD	25	86.2%
CTD		
Rheumatoid Arthritis	1	3.4%
Joint Pain - Unknown	3	10.3%
	29	100.0%

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Table 71: Comparison of Pre- vs. Post-Implant Bra Cup Sizes

Comparison not performed with the reconstruction cohort.

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Table 72: Pre- vs. Post-Implant Bra Size

Comparison not performed with the reconstruction cohort.

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Table 73: Worst Case Physician Assessment of Implants During Each Study Interval

Worst Case Satisfaction Level*
 (Allowable Range 1-5)

Study Interval	Patients	Worst Case Satisfaction Level*				Mean	SD
		Definitely Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Definitely Satisfied		
	n	%	%	%	%		
0-4 Weeks	29	0.0%	0.0%	3.4%	41.4%	4.5	0.6
6 Months	28	3.6%	0.0%	7.1%	39.3%	4.3	0.9
1 Year	26	0.0%	3.8%	0.0%	42.3%	4.5	0.7
2 Years	23	0.0%	4.3%	8.7%	30.4%	4.4	0.8
3 Years	21	4.8%	4.8%	0.0%	23.8%	4.4	1.1
4 Years	21	0.0%	0.0%	4.8%	52.4%	4.4	0.6
5 Years	17	0.0%	5.9%	17.6%	29.4%	4.2	1.0

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied)

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Table 74: Worst Case Patient Assessment of Implants During Each Study Interval

Worst Case Satisfaction Level*
 (Allowable Range 1-5)

Study Interval	n	Worst Case Satisfaction Level*				Mean	SD
		Definitely Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Definitely Satisfied		
		%	%	%	%		
0-4 Weeks	29	0.0%	0.0%	3.4%	34.5%	4.6	0.6
6 Months	28	3.6%	3.6%	7.1%	39.3%	4.2	1.0
1 Year	26	3.8%	7.7%	0.0%	38.5%	4.2	1.1
2 Years	23	0.0%	0.0%	8.7%	34.8%	4.5	0.7
3 Years	21	5.0%	0.0%	10.0%	25.0%	4.4	1.0
4 Years	21	0.0%	0.0%	9.5%	52.4%	4.3	0.6
5 Years	17	0.0%	0.0%	16.7%	22.2%	4.4	0.8

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied)

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Table 75: Patient and Physician Dissatisfactions Specified
Through Five Years

Pt Seq#	Dissatisfaction Specified
1	DUE TO DIFF CONTOUR BTW NATURAL/RECON BR
2	DEVELOPED CAPSULE L,R SOFT NO DISCOM.
2	DISC OPEN CAPSULECTOMY
3	V PLESD W/SHPE,APPNCE DISPLSD W/COMP IMP

**Inamed Corporation
Modular Submission M010040
McGhan Silicone-Filled Breast Implants**

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**Appendix B
Patient Enrollment
by Implanting Site
and Implanting Physician**

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Appendix B: Patient Enrollment by Investigational Site and Implanting Physician

Principal Investigator (Site)	Implanting Physician	Patients (N = 29)	
		n	%
		2	6.9%
		4	13.8%
		1	3.4%
		1	3.4%
		1	3.4%
		4	13.8%
		4	13.8%
		6	20.7%
		<u>10</u>	<u>34.5%</u>
		2	6.9%
		1	3.4%
		1	3.4%
		1	3.4%
		1	3.4%

**Appendix C
Distribution of Product Styles
By Investigator**

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Appendix C1: Distribution of Smooth Product Styles by Investigator

Implanting Physician	N	Total Implants Enrolled		Smooth Styles			
		Style	%	Style	Style	Style	%
	2	40	100.0%	46	80	246	278
	1						

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Appendix C2: Distribution of Textured Product Styles by Investigator

Implanting Physician	n	Total Implants Enrolled			Textured Styles							
		Style 110	Style 120	Style 148	Style 153	Style 156	Style 178	%	%	%		
	2	..	100.0%
	6	66.7%	33.3%	..
	7	100.0%
	1	100.0%
	1	100.0%
	6	100.0%
	8	100.0%
	3	100.0%
	2	100.0%	..
	2	100.0%	..
	2	100.0%